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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,269	02/17/2004	Keith M. Grispo	L-F / 223	2232

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WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/780,269	Applicant(s) GRISPO, KEITH M.	
	Examiner Andrew M. Gilbert	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 7/3/2006. In the reply, applicant amended claims 1, 5, 10, 18, 19, 25 and added new claims 35-39.
2. Thus claims 1-39 are pending with claims 1, 6, 11, 18, 19, 25, and 30 being independent.
3. In response to the reply, a requirement for Restriction has been required.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, drawn to an injector having a plunger driven by a motor, a detector to determine the size and type of a syringe, and a processor and memory acting to move the plunger to a predetermined stop point to purge air from the injector, classified in class 600, subclass 432.
 - II. Claims 6-10, drawn to an injector having a plunger driven by a motor, and a known mechanical clearance between the plunger drive ram and the syringe plunger, and the plunger being driven to a predetermined point to purge air from the injector, classified in class 604, subclass 208.
 - III. Claims 11-17, drawn to an apparatus and method of dual head injector having two syringes, a Y-connector, and a configuration to purge air from the first and second syringes and the Y-connector, classified in class 604, subclass 82.

- IV. Claims 18, 20-24, drawn to a method of purging air from injectors involving filling a syringe and determining the size and type of the syringe, classified in class 128, subclass 898.
- V. Claims 19, 35-39, drawn to a method of automatically purging air from a syringe including filling a syringe, energizing a motor, and purging a known amount of air while factoring in a mechanical clearance present between the plunger drive ram and the syringe plunger, classified in class 604, subclass 123.
- VI. Claims 25-29, drawn to a method of automatically purging air from an injector including monitoring an air detector, energizing a motor to advance a plunger, and stopping the motor when a predetermined condition is reached based upon the monitoring of the air detector, classified in class 604, subclass 67.
- VII. Claims 30-34, drawn to a method of determining the size and type of a first and second syringe, energizing a motor of a first head and second head move the plunger of the first and second syringe respectively to a predetermined purge stop point, classified in class 604, subclass 191.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination III has separate utility such as

injecting two medicants from two different syringes and mixing the components. See MPEP § 806.05(d).

3. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as determined the size and type of the syringe. See MPEP § 806.05(d).

4. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination III has separate utility such as injecting two medicants from two different syringes and mixing the components. See MPEP § 806.05(d).

5. Inventions I and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as being capable of performing an injection of a controlled amount of medicant into the body by a controlled advancement of the plunger drive ram by the motor and processor.

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6. Inventions I and V and VI are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process.

(MPEP § 806.05(e)). In this case invention I can be used to practice another and materially different process such as to determine the size and type of a syringe.

7. Inventions I and VII are directed to related subject matter of purging air from an injector. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions I and VII as claimed are not capable of use together, have a materially different design (one for determine size and type of a single syringe; the other designed for two syringes), have a different mode of operation, function, and effect.

8. Inventions II and IV, V, and VII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process such as being capable of performing

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an injection of a controlled amount of medicant into the body by a controlled advancement of the plunger drive ram by the motor and processor.

9. Inventions II and VII are directed to related subject matter of purging air from an injector. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions II and VII as claimed are not capable of use together, have a materially different design (one for predetermined stroke length of a single syringe; the other designed for two syringes), have a different mode of operation, function, and effect.

10. Inventions III and IV, V, and VI are directed to related subject matter of purging air from an injector. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions III and IV, V, and VI as claimed are not capable of use together, have a materially different design (one for two syringes), have a different mode of operation, function, and effect.

11. Inventions III and VII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus

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as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case invention III as claimed can be used to practice another and materially different process such as controlled mixing of the medicant components of two syringes before injection and then injecting the mixture into the body.

12. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

